UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

RUBICON RESEARCH PRIVATE LIMITED, Plaintiff, v. KARTHA PHARMACEUTICALS INC., and MANOJ BABU MAZHUVANCHERIL, Defendants.	Civil Action No. _____ *Document Electronically Filed*

VERIFIED COMPLAINT FOR DAMAGES, INJUNCTIVE, AND OTHER RELIEF

Rubicon Research Private Limited ("Rubicon"), by and through their counsel, allege for their Complaint against Defendants Kartha Pharmaceuticals, Inc. ("Kartha") and Manoj Babu Mazhuvancheril ("Mazhuvancheril") (collectively "Defendants"), as follows:

NATURE OF THE CASE

1. This is a blatant case of trade secrets theft by Defendant Kartha and its principal, Defendant Manoj Babu Mazhuvancheril. In 2013, Defendants started providing agency and consulting services to third-party Zakłady Farmaceutyczne Polpharma SA ("Polpharma"), which manufactures pharmaceutical ingredients that it supplies to its customers, including Rubicon. Defendants were Polpharma's authorized U.S. representative with the Food and Drug Administration ("FDA"), and, in this capacity, had access to extensive amounts of confidential and trade secret information belonging to Rubicon.

2. More specifically, Defendants had access to the technical specifications for the active pharmaceutical ingredient ("API") Rubicon uses to manufacture its baclofen products that are unique to Rubicon and that were the result of years of Rubicon's research and development efforts, including the technical specifications for Rubicon's 5 mg strength of baclofen.

3. The information concerning Rubicon's 5 mg dose is particularly valuable because Rubicon was the first applicant—generic or branded—to receive FDA approval to sell baclofen in a 5 mg strength. Indeed, until April 2020, Rubicon was the only company approved to sell baclofen 5 mg, and Rubicon has become the market leader in the sales and distribution of this product.

4. In October 2019, Defendants through Polpharma were personally introduced to Rubicon. During this introductory meeting, Polpharma, Defendants, and Rubicon discussed confidential raw material supply, volume, and pricing for various products, including baclofen. The parties also discussed market insights, as is common between supplier and customer, but would never have been discussed if Rubicon knew Defendants could become a competitor.

5. Defendants, not disclosing that it had planned to seek approval from the FDA to sell baclofen, showed specific interest in Rubicon's baclofen program and asked many questions about it, including the genesis of Rubicon's unique idea for introducing a 5 mg strength, the regulatory pathway for this approval, and Rubicon's expected marketing strategy and consequent volume share on the 5 mg strength. As a result of this discussion and subsequent communications thereafter, Defendants also had information about the projected market outlook for this product long before any such data would be publicly available.

6. Unbeknownst to Rubicon and Polpharma, at this same time, Defendants were surreptitiously preparing to seek approval from the FDA to sell baclofen in 5 mg, 10 mg, and 20 mg dosages in direct competition with Rubicon. With intimate knowledge of Rubicon's trade secrets regarding the development, validation, regulatory approval, market introduction and commercial potential of baclofen products, Defendants prepared and filed an application to manufacture baclofen products that was quickly approved by the FDA in March 2021, despite the fact that this was Defendants' first approval from the FDA to sell any drug product.

7. As a result of the FDA's approval of Defendants' baclofen application and Rubicon's investigation, Rubicon is informed and believes that Kartha will commercialize its competing baclofen drug products using Rubicon's confidential and proprietary trade secrets, actions that will irreparably harm Rubicon if not enjoined.

8. In light of these actions, Rubicon has no choice but to bring this action to prevent Kartha from unfairly competing and improperly usurping Rubicon's significant investment in baclofen products.

THE PARTIES

9. Plaintiff Rubicon is a private limited company incorporated under the Companies Act, 1956 of the Republic of India bearing Corporate Identification Number (CIN) U73100MH1999PTC119744 and with its registered office at MedOne House, B75, Road No 33, Wagle Estate, Thane (West), Maharashtra 400604, India.

10. Third-Party Zakłady Farmaceutyczne Polpharma SA ("Polpharma") is a corporation organized under the laws of Poland with its principal place of business in Starogard Gdanski, Poland.

11. Rubicon is informed and believes that defendant Kartha Pharmaceuticals Inc. is incorporated in North Carolina and has its principal place of business at 12208 Summer Breeze Court, Charlotte, North Carolina.

12. Kartha Pharmaceuticals Inc. is the successor entity to Kartha Pharmaceutics, LLC.

13. Rubicon is informed and believes that defendant Manoj Babu Mazhuvancheril is a resident of Charlotte, North Carolina. Mazhubancheril is Kartha's President and Chief Executive Officer of Kartha.

14. Rubicon is informed and believes that the Defendants were the agents, servants, and employees of each other, and were acting within the course and scope of their authority as

such agents, servants, and employees and with the permission and consent of each of them at all relevant times alleged herein. In particular, Rubicon is informed and believes that Defendant Mazhuvancheril has acted and is presently acting as the agent and/or employee of Kartha and working on its behalf.

JURISDICTION AND VENUE

15. This action arises under the Defend Trade Secrets Act of 2016, 18 U.S.C. §§ 1836, *et seq*. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, and has supplemental jurisdiction over the state law claims alleged in this Complaint pursuant to 28 U.S.C. § 1367.

16. This Court has personal jurisdiction over Defendants because each of them is domiciled in or has its principal place of business in Charlotte, North Carolina.

17. As is further set forth herein, a substantial part of the events or omissions giving rise to the claims alleged in this Complaint occurred and have a direct effect in this District. Venue therefore lies in the United States District Court for the Western District of North Carolina pursuant to 28 U.S.C. § 1391(b)(2).

GENERAL ALLEGATIONS

A. Rubicon Obtains ANDA Approval for Baclofen.

18. Rubicon is a pharmaceutical company focused on developing high quality products using innovative technologies for the global market, including the United States. Rubicon develops and manufactures over two dozen different finished drug products. One of its most profitable and important products is baclofen, which is used to treat spasticity and concomitant pain, clonus, and muscular rigidity in people with multiple sclerosis or with spinal cord injuries.

19. To market a generic version of any previously-approved drug product in the United States, a generic pharmaceutical company must file an abbreviated new drug application

("ANDA") with the United States Food and Drug Administration ("FDA") that shows the product's chemical and biological equivalence to a previously-approved drug product (known as the "reference listed drug" or "RLD"). *Id*. (citing 21 U.S.C. § 355(j)(2)(A)). This well-established regulatory pathway establishes the safety and efficacy of generic drugs.

20. To gain approval, the FDA must be satisfied that the finished drug product manufactured by the generic pharmaceutical company contains the same active ingredient, employs the same route of administration (*e.g.*, oral or injected), is in the same dosage form and the same strength, and "ha[s] the same therapeutic effect" as the branded equivalent on which the ANDA is based. 21 U.S.C. § 355(j)(2)(A)(i)-(iv).

21. To make these showings, generic pharmaceutical companies must submit scores of information and data about the drug and describe in detail how it will be manufactured. ANDA applications typically include sections on chemistry, manufacturing and controls ("CMC"), clinical/bioequivalence studies, quality aspects of the drug substance and the drug product, non-clinical study reports, and references to scientific publications. The ANDA application also must include the ingredients used to manufacture the drug and, specifically, very detailed information about the API, such as its particle size distribution and the location from where it is sourced. The ANDA application also includes information on how the drug maintains its stability (or efficacy) over time when stored in certain conditions. To obtain this data, the ANDA applicant must submit the results of stability testing that it conducted on the finished drug product that it has actually manufactured. This requirement means that the generic pharmaceutical company must manufacture batches of the finished drug product, and then conduct testing on the drug product as it is stored over time.

22. Given all the information required to submit an ANDA, they are often hundreds of pages or longer and it often takes more than a year—and sometimes several years—for a generic pharmaceutical company to prepare an ANDA. Then, given the extensive information that must be reviewed by the FDA, it is common for an ANDA approval to take twelve months before FDA approval is granted, provided the FDA does not request additional information.

23. In March 2014, in preparing its ANDA application for baclofen, Rubicon signed a Mutual Confidential Disclosure Agreement ("CDA") with Polpharma to enable the parties to evaluate potential opportunities to collaborate on baclofen. Rubicon needed a supplier for baclofen API to incorporate into its ANDA application and Polpharma was the leading supplier of baclofen API in the world, supplying close to 80% of all baclofen API to various generic pharmaceutical companies.

24. The CDA provided that the parties would treat all confidential information as strictly confidential; would not disclose confidential information to any third party; and would not use confidential information for any purpose other than evaluating the potential opportunities for Rubicon and Polpharma to collaborate on baclofen. The parties further agreed only to disclose confidential information to authorized recipients who needed to know the confidential information for purposes of evaluating or advising on potential opportunities to collaborate on baclofen. These obligations were in force for five years.

25. Rubicon and Polpharma decided to collaborate on baclofen. Polpharma agreed to supply baclofen API to Rubicon and Rubicon therefore indicated on its ANDA application that Polpharma would be its supplier and referenced the Drug Master File ("DMF") that Polpharma keeps on file with the FDA, which details how Polpharma manufactures the API, as required by

the FDA. To enable Rubicon's use of the DMF, Popharma issued a letter of access, which was known to Defendants, by virtue of their engagement as the U.S. regulatory agent for Polpharma.

26. In May 2016, after investing substantial amounts of time and money to satisfy the FDA's requirements, Rubicon submitted an ANDA application to manufacture and sell baclofen in the 5 mg, 10 mg, and 20 mg doses.

27. Rubicon's application was the first to seek approval to manufacture and sell baclofen in the 5 mg strength. This creative idea gave Rubicon a competitive edge but also made the ANDA application more complicated, because it was seeking approval for a dosage that had not been approved before.

28. Rubicon's creativity and substantial investment was rewarded in November 2017, when the FDA approved Rubicon's ANDA for baclofen in the 5 mg, 10 mg, and 20 mg doses, issuing ANDA No. 2019102.

29. Rubicon was then approved to supply baclofen to customers in the United States and became the first and only manufacturer and supplier of baclofen 5 mg in the United States.

30. Rubicon has devoted significant time and resources researching, developing, and validating its baclofen products. This process involved years of effort and collaboration across different departments, including laboratory research, formulation development, and analytical development.

B. Rubicon's Trade Secrets and Its Extensive Measures to Protect Them.

31. Rubicon's development of baclofen, including the work performed as part of ANDA No. 209102, as well as Rubicon's ongoing efforts to manufacture and sell its baclofen products has produced a substantial amount of highly sensitive and proprietary trade secret information, the confidentiality of which is critical to the significant value that these products

represent to Rubicon. Included among these trade secrets is technical specifications of its baclofen API, including but not limited to the particle size, bulk density, and tapped density, as well as confidential information relating to the manufacture, distribution, marketing, and sale of its baclofen products, industry competitive intelligence, strategic plans, results of operations, and short and long-term business strategies and initiatives (collectively, the "Trade Secrets").

32. To protect the confidentiality of the Trade Secrets, Rubicon has implemented numerous security measures. For example, Rubicon's physical facilities are enclosed by brick wall fences and monitored 24 hours a day by surveillance cameras and manned patrols. Entry to and exit from Rubicon facilities is controlled, and access is allowed only to authorized individuals. Within Rubicon's facilities, tangible copies of Trade Secret information are maintained in secured and locked locations, access to which is limited to those with a need to know and who use the Trade Secrets in the development and manufacturing process.

33. Rubicon maintains certain Trade Secrets in the form of electronic records that are accessible via the Rubicon secure computer network. Access to that network is limited to Rubicon employees, and access to electronically stored Trade Secret information on that network is password protected and monitored by Rubicon security personnel. All relevant Rubicon employees are required to read, acknowledge, and execute a confidentiality agreement as a condition of, and in consideration for, their employment, by which they agree not to disclose any confidential or proprietary information to anyone outside of the company, and not to use any of that information in connection with work performed for any future employer.

34. Rubicon has also implemented corporate policies and trainings to protect its Trade Secrets and other confidential information, including information technology security guidelines that, *inter alia*, strictly limit the downloading, copying, or distribution of the company's

confidential information by its employees, except as specifically authorized and required for the performance of the employee's duties.

35. Rubicon also requires third parties, such as partners, vendors, and suppliers to sign non-disclosure agreements.

C. Rubicon's Relationship with Polpharma and Kartha

36. After Rubicon received its ANDA for baclofen in November 2017, its relationship with Polpharma expanded, as Polpharma agreed to supply all of Rubicon's baclofen API and Rubicon continued to increase its sales of baclofen.

37. In August 2019, Polpharma and Rubicon executed a Supply Agreement that renewed Polpharma's agreement to supply Rubicon with all of its baclofen API. Indeed, Rubicon was required to order certain minimum quantities of baclofen API.

38. Similar to the CDA the parties executed in March 2014, The Supply Agreement contained a robust confidentiality provision that stated "[n]either Party shall disclose to any third party Confidential Information, without prior consent of the disclosing Party . . . as well as each Party shall use it only for proper performance of the Agreement." The Supply Agreement further provided that "[t]he receiving Party agrees not to disclose such Confidential Information to anyone except its own directors, officers, employees, attorneys, advisors, Affiliates and subcontractors (Personnel) who: (i) know such information as well as (ii) are bound by confidentiality, non-use, and nondisclosure obligations at least as restrictive as those set forth in this Agreement." All obligations related to confidentiality, non-use and nondisclosure under the Supply Agreement "shall survive for a period of five (5) years from the date of expiry or termination of the [Supply] Agreement."

39. During this time, Kartha was providing services to Polpharma. The relationship between Polpharma and Kartha dates back to September 2, 2013 when Polpharma first entered

into a Consulting Services Agreement with Kartha for it—through Mazhuvancheril—to provide services at the request of and for the benefit of Polpharma in a professional and competent manner. Kartha then became Polpharma's U.S. authorized representative with the FDA.

40. In their capacity as Polpharma's U.S. representative providing these services to Polpharma, Defendants had access to Rubicon's Trade Secrets.

41. In November 2015, Polpharma and Kartha extended their relationship by executing an Amendment on Consulting Services Agreement that extended the September 2013 agreement for two years and provided for automatic renewals thereafter.

42. Upon information and belief, the Consulting Services Agreement and its amendments contained robust confidentiality provisions.

43. Although Defendants already had access to Rubicon's Trade Secrets, in October 2019, Polpharma personally introduced Rubicon to Mazhuvancheril, and thus Kartha, at CPhI, an annual industry conference for pharmaceutical professionals and companies.

44. During this introductory meeting, Polpharma, Defendants, and Rubicon discussed Rubicon's Trade Secrets, specifically confidential raw material supply, volume, and pricing for various products, including baclofen as well as market insights.

45. Defendants showed a particularly keen interest in Rubicon's baclofen program and asked many questions about it, including the genesis of Rubicon's unique idea for introducing a 5 mg strength, the regulatory pathway for this approval, and Rubicon's expected marketing strategy and consequent volume share on the 5 mg strength.

46. Thereafter, from October 2019 onwards, Mazhuvancheril began working directly with Rubicon and obtained Rubicon's Trade Secrets from both Polpharma and directly from Rubicon. Mazhuvancheril specifically had access to Polpharma generated certificates of analysis

for the baclofen API supplied to Rubicon for the 5 mg, 10 mg and 20 mg doses. These certificates of analysis contain details of the particle size distribution ("PSD") and tap density and bulk density ("TD and BD") of the product. Rubicon specifically shared detailed information about Rubicon's formulations for 5 mg, 10 mg and 20 mg doses of baclofen as well as volume forecasts.

47. During this time, Mazhuvancheril showed significant interest in the technical aspects of Rubicon's baclofen formulations, especially PSD and TD and BD and why these were selected.

48. The PSD is a critically important aspect of Rubicon's baclofen formulation because physicochemical and biopharmaceutical properties of drug substances and dosage forms can be highly affected by the particle size, a critical process parameter in pharmaceutical production. Indeed, the PSD of the drug substance may have significant effects on final drug product performance (e.g., dissolution, bioavailability, content uniformity, stability, etc.). PSD data is particularly useful in developing a successfully bioequivalent formulation of this product. Rubicon developed its own PSD data for baclofen, which Defendants knew as a result of their access to Rubicon's Trade Secrets.

49. The TD and BD of a pharmaceutical ingredient refers to the maximum packing density of a powder that is achieved under the influence of an externally applied force, i.e., when mechanically compressing the API into a tablet. This is an important data point in the tablet production process wherein loose powders are compacted into a durable solid form with the desired mechanical strength, porosity and dissolution characteristics – all of which are critical in pharmaceutical formulations that must conform to set performance parameters in a consistent manner.

50. At no time during his communications with Rubicon did Defendants disclose that they were preparing their own baclofen ANDA application

51. Having Rubicon's PSD and TD/BD specifications as well as Rubicon's own forecasts for baclofen, particularly its market outlook for the 5 mg dose which was exclusively marketed by Rubicon provided a road map to Defendants to develop a competing product, which Defendants misappropriated from Rubicon.

D. Rubicon's Discovery of Kartha's Misappropriation of the Trade Secrets.

52. In March 2021, Rubicon first learned that, at some point after December 2019, Kartha submitted an ANDA application (ANDA No. 214374) for baclofen 5 mg, 10 mg, and 20 mg doses that was approved by the FDA on March 5, 2021.

53. According to publicly available information, Kartha's baclofen ANDA application was the first ANDA approval Kartha has ever received for any drug formulation.

54. Rubicon discovered that Kartha formed an Indian subsidiary, Kartha Pharmaceuticals Private Limited ("Kartha Ltd."), in September 2019. Kartha Ltd. is registered in Bangalore as a subsidiary of a foreign company and it is involved in the manufacture of chemical products. The directors of Kartha Ltd. are Mazhuvancheril and his wife, Karthika Manoj Mazhuvancheril.

55. Mazhuvancheril, through his role at Kartha as a contractor for Polpharma, had access to Rubicon's Trade Secrets and other confidential information. He was involved in and exposed to, for example, Rubicon's baclofen API information, including its unique PSD, as well as confidential information relating to the highly sensitive pricing and quantities of baclofen API for the manufacture of Rubicon's baclofen products and Rubicon's market plan and forecast regarding demand and volume forecasts.

56. Upon information and belief, Kartha used Rubicon's Trade Secrets to prepare its ANDA application for baclofen.

57. Rubicon is informed and believes and on that basis alleges that given Mazhuvancheril's—and therefore Kartha's—exposure to voluminous Rubicon confidential and proprietary information, it would be impossible for Mazhuvancheril to have prepared an ANDA application for baclofen products that would directly compete with Rubicon baclofen products without using Rubicon's Trade Secrets.

58. Upon information and belief, these allegations demonstrating Defendants' misconduct are only the tip of the iceberg, and expedited discovery of Kartha's, Mazhuvancheril's and their financial backers' internal emails, documents, electronic records, and testimony under oath of Kartha principals, along with various other forms of discovery, will uncover much more, similar evidence.

59. Based on the information provided above, Rubicon is informed and believes that Kartha has used or will use Rubicon's Trade Secrets and other confidential information to commercialize baclofen products. In fact, now that Kartha has obtained an ANDA for baclofen products, Rubicon is informed and believes that Kartha will be in the position to start contacting customers and distribution channels in the next month or two in direct competition with Rubicon's baclofen products, having used Rubicon's Trade Secrets to do so.

60. Even more critically, Defendants have knowledge of Rubicon's interest and efforts with respect to three additional products presently under development, and based on the forgoing conduct, Rubicon believes that this information may be at risk as well.

COUNT I

Violation of Federal Defend Trade Secrets Act, 18 U.S.C. § 1836 (*Against All Defendants*)

61. Rubicon re-alleges each and every allegation set forth in Paragraphs 1 through 60, inclusive, and incorporates them herein by reference.

62. Rubicon is the owner of Trade Secrets and other proprietary or confidential information relating to baclofen products. These Trade Secrets are described generally above and comprise financial, business, scientific, technical, economic, and/or engineering information that are used in or intended for use in interstate commerce and that accordingly constitute "trade secrets" under 18 U.S.C. § 1839(3).

63. Rubicon has taken reasonable steps to maintain the secrecy of its Trade Secrets, including by, among other things, requiring confidentiality and/or nondisclosure agreements to be signed by those granted access to Rubicon's Trade Secrets and by taking the other reasonable measures described above.

64. These confidential and proprietary Trade Secrets derive independent economic value from not being generally known to or readily ascertainable through proper means by another person who can obtain economic value from the disclosure and use of such information, and have conferred a competitive advantage on Rubicon over others in the relevant market.

65. Other than through Defendants' improper disclosure, the Trade Secrets are not known to others and are not readily ascertainable by proper means to persons who could derive value from their disclosure or use.

66. Defendants misappropriated Rubicon's Trade Secrets by improper means and without authorization, including by disclosing and using and/or threatening to disclose and use the Trade Secrets without Rubicon's express or implied consent in the preparation and filing of an ANDA application for baclofen 5 mg, 10 mg, and 20 mg, and by using Rubicon's pricing, market,

and volume information to commercialize its baclofen product, as well as the other ways described above.

67. The Defendants' actual and threatened use and disclosure of the Trade Secrets constitutes misappropriation because, among other reasons, at the time of such use and disclosure, the Defendants knew or had reason to know that their knowledge of the Trade Secrets was derived through persons who owed a duty to Rubicon and Polpharma to maintain the secrecy of the Trade Secrets.

68. Defendants' misappropriation comprises acts, including without limitation use of Rubicon's Trade Secrets, on or after the date of the enactment of the Defend Trade Secrets Act, May 11, 2016.

69. Defendants' current and continued misappropriation of Rubicon's Trade Secrets is reckless and malicious. Defendants know of the confidentiality, ownership, and use restrictions on the Trade Secrets.

70. By reason of the above-alleged acts and conduct of Defendants, Rubicon has been damaged, and it will continue to suffer great and irreparable harm and damage. The amount of this irreparable harm will be difficult if not impossible to ascertain, and Rubicon will be without an adequate remedy at law.

71. Rubicon is also entitled to recover compensatory and exemplary damages from Defendants, including but not limited to the losses resulting from their wrongful conduct and any unjust enrichment caused by their misappropriation. The amount of such relief cannot be determined precisely at this time.

COUNT II

Violation of The North Carolina Trade Secrets Protection Act, N.C.G.S.A. § 66-152, et seq. (*Against All Defendants*)

72. Rubicon re-alleges each and every allegation set forth in Paragraphs 1 through 71 inclusive, and incorporates them herein by reference.

73. Rubicon is the owner of Trade Secrets and other proprietary or confidential information relating to baclofen products. These Trade Secrets are described generally above and are comprised of business or technical information, including but not limited to a formula, pattern, program, device, compilation of information, method, technique, or process that constitute "trade secrets" under N.C.G.S.A. § 66-152

74. Rubicon has taken reasonable steps to maintain the secrecy of its Trade Secrets, including by, among other things, requiring confidentiality and/or nondisclosure agreements to be signed by those granted access to Rubicon's Trade Secrets and by taking the other reasonable measures described above.

75. These confidential and proprietary Trade Secrets derive independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, others who can obtain economic value from its disclosure or use, and have conferred a competitive advantage on Rubicon in the relevant market.

76. Other than through Defendants' improper disclosure, the Trade Secrets are not known to the public and are not readily ascertainable by proper means to persons who could derive value from their disclosure or use.

77. Defendants misappropriated Rubicon's Trade Secrets by improper means and without authorization, including by disclosing and using and/or threatening to disclose and use the Trade Secrets without Rubicon's express or implied consent in the preparation and filing of an ANDA application for baclofen 5 mg, 10 mg, and 20 mg, and by using Rubicon's pricing, market and volume information to commercialize its baclofen product.

78. The Defendants' actual and threatened use and disclosure of the Trade Secrets constitutes misappropriation because at the time of such use and disclosure, the Defendants knew or had reason to know that their knowledge of the Trade Secrets was derived through persons who owed a duty to Rubicon to maintain the secrecy of the Trade Secrets.

79. Defendants' current and continued misappropriation of Rubicon's Trade Secrets is willful and malicious. Defendants know of the confidentiality, ownership, and use restrictions on the Trade Secrets.

80. By reason of the above-alleged acts and conduct of Defendants, Rubicon has been damaged, and it will continue to suffer great and irreparable harm and damage. The amount of this irreparable harm will be difficult if not impossible to ascertain, and Rubicon will be without an adequate remedy at law.

81. Rubicon is also entitled to recover compensatory and punitive damages from Defendants, including but not limited to the losses resulting from their wrongful conduct and any unjust enrichment caused by their misappropriation. The amount of such relief cannot be determined precisely at this time.

COUNT III
Violation of The North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S.A. § 75-1.1 (*Against All Defendants*)

82. Rubicon re-alleges each and every allegation set forth in Paragraphs 1 through 81, inclusive, and incorporates them herein by reference.

83. Rubicon is the owner of Trade Secrets and other proprietary or confidential information relating to baclofen products.

84. Rubicon has taken reasonable steps to maintain the secrecy of its Trade Secrets, including by, among other things, requiring confidentiality and/or nondisclosure agreements to be

signed by those granted access to Rubicon's Trade Secrets and by taking the other reasonable measures described above.

85. These confidential and proprietary Trade Secrets derive independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, others who can obtain economic value from its disclosure or use, and have conferred a competitive advantage on Rubicon in the relevant market.

86. Defendants improperly and unfairly disclosed and used these Trade Secrets and confidential information by improper means and without authorization, including by disclosing and using and/or threatening to disclose and use the Trade Secrets and confidential information without Rubicon's express or implied consent in the preparation and filing of an ANDA application for baclofen 5 mg, 10 mg, and 20 mg, and by using Rubicon's pricing, market and volume information to commercialize its baclofen product, as well as the other ways described above—all in an effort to unfairly directly competing with Rubicon.

87. Defendants actions directly affect commerce because in March 2021, the FDA approved Kartha's ANDA application for baclofen 5 mg, 10 mg, and 20 mg doses and thus Kartha will commercialize baclofen products in a matter of months and used Rubicon's confidential pricing, market, and volume information to directly compete with Rubicon.

88. Kartha has and will continue to unfairly exploit Rubicon's Trade Secrets and confidential information by using them without authority, including in the commercialization of competing baclofen products.

89. By reason of the above-alleged acts and conduct of Kartha, Rubicon has been damaged, and it will continue to suffer great and irreparable harm and damage. The amount of this

irreparable harm will be difficult if not impossible to ascertain, and Rubicon will be without an adequate remedy at law.

90. Rubicon is also entitled to recover compensatory and punitive or treble damages from Defendants. The amount of such relief cannot be determined precisely at this time.

COUNT IV

Unfair Competition, North Carolina Common Law (*Against all Defendants*)

91. Rubicon re-alleges each and every allegation set forth in Paragraphs 1 through 90, inclusive, and incorporates them herein by reference.

92. Rubicon is the owner of Trade Secrets and other proprietary or confidential information relating to baclofen products.

93. Rubicon has taken reasonable steps to maintain the secrecy of its Trade Secrets, including by taking reasonable measures to protect its Trade Secrets as described herein.

94. These confidential and proprietary Trade Secrets derive independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, others who can obtain economic value from its disclosure or use, and have conferred a competitive advantage on Rubicon in the relevant market.

95. Defendants improperly and unfairly disclosed and used these Trade Secrets and confidential information by improper means and without authorization, including by disclosing and using and/or threatening to disclose and use the Trade Secrets and confidential information without Rubicon's express or implied consent in the preparation and filing of an ANDA application for baclofen 5 mg, 10 mg, and 20 mg, and by using Rubicon's pricing, market, and volume information to commercialize its baclofen product, as well as the other ways described above—all in an effort to unfairly directly competing with Rubicon.

96. Defendants actions directly affect commerce because in March 2021, the FDA approved Kartha's ANDA application for baclofen 5 mg, 10 mg, and 20 mg doses and thus Kartha will commercialize baclofen products in a matter of months and use Rubicon's confidential pricing, market, and volume information to directly compete with Rubicon.

97. Kartha has and will continue to unfairly exploit Rubicon's Trade Secrets and confidential information by using them without authority, including in the commercialization of competing baclofen products.

98. By reason of the above-alleged acts and conduct of Defendants, Rubicon has been damaged, and it will continue to suffer great and irreparable harm and damage. The amount of this irreparable harm will be difficult if not impossible to ascertain, and Rubicon will be without an adequate remedy at law.

99. Rubicon is also entitled to recover compensatory and punitive damages from Defendants. The amount of such relief cannot be determined precisely at this time.

COUNT V
Breach of Fiduciary Duty, North Carolina Common Law (*Against all Defendants*)

100. Rubicon re-alleges each and every allegation set forth in Paragraphs 1 through 99, inclusive, and incorporates them herein by reference.

101. Defendants each owed, and continue to owe, a fiduciary duty to Rubicon because, among other reasons, Rubicon entrusted them with access to the Trade Secrets and other confidential information and because Defendants were bound to act in good faith and with due regard to Rubicon's interests, especially considering Defendants owed specific duties of confidence and good faith to Polpharma.

102. Defendants fiduciary duties included, among others, the duty to protect the confidentiality of Rubicon's Trade Secrets and other confidential information and to refrain from

unfairly competing with Rubicon by using Rubicon's Trade Secrets and other confidential information.

103. Defendants have knowingly breached their fiduciary obligation to Rubicon by disclosing and/or using Rubicon's Trade Secrets and other confidential information for their benefit in the preparation and filing of an ANDA application for baclofen 5 mg, 10 mg, and 20 mg doses and in the commercialization of baclofen, as well as the other acts described above.

104. By reason of the above-alleged acts and conduct of Defendants, Rubicon has been damaged, and it will continue to suffer great and irreparable harm and damage. The amount of this irreparable harm will be difficult if not impossible to ascertain, and Rubicon will be without an adequate remedy at law.

105. Rubicon is also entitled to recover compensatory damages and punitive damages from Defendants. The amount of such relief cannot be determined precisely at this time.

COUNT VI

Unjust Enrichment, North Carolina Common Law (*Against all Defendants*)

106. Rubicon re-alleges each and every allegation set forth in Paragraphs 1 through 105, inclusive, and incorporates them herein by reference.

107. Rubicon is the owner of Trade Secrets and other proprietary or confidential information relating to baclofen products.

108. Rubicon has taken reasonable steps to maintain the secrecy of its Trade Secrets, including by, among other things, requiring confidentiality and/or nondisclosure agreements to be signed by those granted access to Rubicon's Trade Secrets and by taking the other reasonable measures described above.

109. These confidential and proprietary Trade Secrets derive independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable

through proper means by, others who can obtain economic value from its disclosure or use, and have conferred a competitive advantage on Rubicon in the relevant market.

110. Rubicon conferred a benefit on Defendants by allowing them access to the Trade Secrets and confidential information for purposes of Defendants performing their consulting obligations to Polpharma, not for any gratuitous purpose or for Defendants to develop and commercialize competing baclofen products.

111. Defendants accepted this benefit under the guise of performing their consulting obligations to Polpharma.

112. Defendants were thus unjustly enriched when they improperly used their access to the Trade Secrets and confidential information in the preparation and filing of an ANDA application for baclofen 5 mg, 10 mg, and 20 mg, and by using Rubicon's pricing, market, and volume information to commercialize its baclofen product, as well as the other ways described above.

113. By reason of the above-alleged acts and conduct of Defendants, Rubicon has been damaged, and it will continue to suffer great and irreparable harm and damage. The amount of this irreparable harm will be difficult if not impossible to ascertain, and Rubicon will be without an adequate remedy at law.

114. Rubicon is also entitled to recover compensatory and punitive damages from Defendants. The amount of such relief cannot be determined precisely at this time.

RELIEF SOUGHT

WHEREFORE, Rubicon prays for judgment against Defendants, and each of them, as follows:

1. An injunction restraining the Defendants, as well as their employers, agents,

employees, and all persons acting in concert with them, from using, copying, publishing, disclosing, transferring, or selling Rubicon's Trade Secrets or other confidential proprietary information that may be determined not to be Trade Secret information, or any product that is based on or incorporates part or all of Rubicon's Trade Secrets or other confidential proprietary information, and from obtaining any commercial advantage or unjust enrichment from their misappropriation of Rubicon's Trade Secrets or other confidential and proprietary information;

2. An order requiring Defendants, their employers, agents, employees, and all persons acting in concert with them, to return to Rubicon any and all of its Trade Secrets and other confidential, proprietary materials that may be determined not to be Trade Secret information, including but not limited to any and all materials created incorporating or referencing Rubicon's Trade Secrets and other confidential information;

3. During the pendency of this action, an injunction enjoining and restraining Defendants from destroying, manipulating, or otherwise altering any evidence, including evidence that may reside on (or be embodied by changes to) any computer system, network, or other electronic means of data storage or transfer, relating in any way to the matters alleged in this Complaint;

4. Rubicon be awarded damages caused by Defendants' conduct, including punitive, treble, and exemplary damages as applicable and interest;

5. Reasonable attorneys' fees;

6. All costs of suit herein incurred; and

7. Such other and further relief as the Court may deem proper.

DATED: March 30, 2021

Respectfully Submitted,

/s/ Ross R. Fulton

Ross R. Fulton (N.C. State Bar No. 31538)
RAYBURN COOPER & DURHAM, P.A.
227 West Trade Street, Suite 1200
Charlotte, NC 28202
Tel: (704) 334-0891
Fax: (704) 377-1897
rfulton@rcdlaw.net

Leigh Ann Buziak
Ann E. Querns
(pro hac vice applications forthcoming)
BLANK ROME LLP
One Logan Square
130 N. 18th Street
Philadelphia, PA 19103
Tel: (215) 569-5600
FAX: (215) 832-5600
lbuziak@blankrome.com
aquerns@blankrome.com

Attorneys for Plaintiff
Rubicon Research Private Limited

VERIFICATION

I, Parag Sancheti, in my capacity as CEO, hereby state that I am familiar with the facts set forth in the foregoing Verified Complaint, am authorized to execute this Verification on behalf of Plaintiff Rubicon Research Private Limited, and that the facts set forth therein are true and correct to the best of my knowledge, information and belief.

This Verification is made subject to the penalties of 28 U.S.C. § 1746 for unsworn falsification to authorities.

Parag Sancheti

Dated: March 27, 2021